

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

MEMORANDUM

6/3/2019

SUBJECT: Product Chemistry Review for **Organipeel** EPA Reg. No.: **92708-R**

FROM: Lynette T. Umez-Eronini
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Lynette T. Umez-Eronini

THRU: Karen P. Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510P)

Karen P. Hicks

TO: Jacqueline Hardy, PM Team 34 / Lorena Rivas
Regulatory Management Branch II
Antimicrobials Division (7510P)

Registrant: Apeel Sciences
Action code: A540
Agency Due Date:
6/7/2019
DP No.: 450702
Submission No.: 1029216
E-Sub No.: 35138
Classification: EP
Process: Integrated
system
Pesticide type:
Antimicrobial

MRID(s):50748200, 50748201, 50748202, 50748203, 50748204, 50866001

Formulation from label			
PC code(s)	CAS #(s)	Active Ingredient(s)	% weight
021801	77-92-9	Citric Acid	.66
		Other Ingredients	99.34
		Total	100

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I. BACKGROUND

The Registrant, Apeel Sciences, has submitted an application for pesticide registration for their product: Organipeel EPA Reg. No. 92708-R.

II. RELEVANT DOCUMENTS

	RECEIVED	N/A
EPA FORM 8570-1 Application for Pesticide Registration (12/14/2018)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EPA FORM 8570-27 – Formulator’s Exemption Statement	<input type="checkbox"/>	<input checked="" type="checkbox"/>
EPA FORM 8570-34 – Certification with Respect to Citation of Data (5/24/2019)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EPA FORM 8570-35 – Data Matrix (5/24/2019)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
EPA FORM 8570-36 – Summary of the Physical/Chemical Properties (PR Notice 98-1) (5/24/2019)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Cover letter (12/14/2018)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Transmittal document (12/14/2018)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Proposed CSF BASIC, (5/24/2019)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Proposed label, (5/24/2018)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Certification for Pilot Fragrance Notification Program	<input type="checkbox"/>	<input checked="" type="checkbox"/>
E-mails from Registrant, (5/24/2019)	<input checked="" type="checkbox"/>	<input type="checkbox"/>
REFERENCED: CSF	--	
Comments: E-mails from Registrant, dated 5/24/2019 addressed Group A Product Chemistry requirements.		

III. FINDINGS

a. Product Formulation:

	TGAI	MUP	EUP	Food use	Non-food use
Non-integrated	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Integrated	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Active Ingredients(s)			Nominal	Upper limit	Lower limit
Citric acid			0.66%	0.72%	0.59%

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	YES	NO	N/A
1. The certified limits of all ingredients are within 40 CFR standard certified limits.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
2. Wider certified limits were requested and rationale was accepted.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
3. The nominal concentration(s) of the active ingredient is in agreement with the label.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
4. The chemical IDs and analytical information for density, pH, and flammability are consistent with Series 830 Group B data.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5. All inert ingredients are approved for food use pesticide formulations.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The impurities present >0.1% are identified.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7. Impurities of toxicological significance have an upper certified limit.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

b. Product Label:

	Yes	NO	N/A
<i>The formula contains one of the following:</i>			
1. 10% or more of petroleum distillate	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
2. 1.0% or more of methyl alcohol	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3. Sodium nitrite at any level	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
4. A toxic list 1 inert at any level	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5. Arsenic in any form	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6. If yes to 1-5, then the inert ingredient list contains a relevant footnote	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7. Appropriate warning statements regarding flammability or explosive characteristics of the product are included on the label	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
8. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. The product requires an expiration date at which time the nominal concentration falls below the lower certified limit.	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

IV. Additional Findings

1. MRID 50866001 replaces MRID 50748201 (email, dated 5/29/2019).
2. Group A product chemistry data requirements applicable to end-use product have been met (see MRID 50866001 and 50748204 on Table A).
3. Group B product chemistry data requirements applicable to end-use product have been met (see MRID 50748202 and 50748203 and EPA Form 8570-36 on Table B).

V. Conclusion

The Product Science Branch of Antimicrobials Division finds Group A and B Product Chemistry Data requirements have been met. Basic CSF dated 5/24/2019 is acceptable.

VI. Table A:
Series 830 guidelines – Group A

OPPTS#	Name	Status	MRID
830.1550	Product Identity & Composition	Acceptable	50866001
830.1600	Description of materials	Acceptable	50866001
830.1620	Description of production process	Acceptable	50866001
830.1650	Description of formulation process	Acceptable	50866001
830.1670	Discussion of formation of impurities	Acceptable	50866001
830.1700	Preliminary analysis	Acceptable	50866001
830.1750	Certified limits	Acceptable	50866001
830.1800	Enforcement analytical method	Acceptable	50748204
830.1900	Submittal of samples	Acceptable	50866001

VII. Table B: Series 830 guidelines – Group B

OPPTS#	Name	Study Findings/Comment		Status	MRID
830.6302	Color	Not required for end use product		Not applicable	N/A
830.6303	Physical state	solid		Acceptable	50748202
830.6304	Odor	Not required for end use product		Not applicable	N/A
830.6313	Stability to normal & elevated temperatures, metals & metal ions	Not required for end use product		Not applicable	N/A
830.6314	Oxidation/Reduction	Registrant reported not applicable. Product does not contain oxidizing or reducing agents.		Acceptable	EPA Form 8570-36
830.6315	Flammability	Registrant reported not applicable. Product is not composed of flammable materials.		Acceptable	EPA Form 8570-36
830.6316	Explodability	Registrant reported not applicable. Product is not composed of explodable materials.		Acceptable	EPA Form 8570-36
830.6317	Storage stability (14-Day Accelerated Study)	Time, day	[Average Citric Acid], %	Acceptable	50748203
		0	0.62		
		14	0.61		
		The concentration of active ingredient falls within EPA Standard Certified Limits (0.72 - 0.59).			
830.6319	Miscibility	Registrant reported not applicable. Product is a solid powder.		Acceptable	EPA Form 8570-36
830.6320	Corrosion characteristics (14-Day Accelerated Study)	No corrosion of storage container (paper) was observed.		Acceptable	50748203
830.6321	Dielectric breakdown voltage	Registrant reported not applicable. Not intended for		Acceptable	EPA Form 8570-36

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		use in or around electrical equipment.		
830.7000	pH	8.44	Acceptable	50748202 & EPA Form 8570-36
830.7050	UV/Visible absorption	Not required for MUP or EP	Not applicable	N/A
830.7100	Viscosity	Not applicable – Product is a solid powder.	Acceptable	EPA Form 8570-36
830.7200	Melting point	Not required for MUP or EP	Not applicable	N/A
830.7220	Boiling point	Not required for MUP or EP	Not applicable	N/A
830.7300	Density/relative	0.5 g/ml – Pour density 0.6g/ml – Tap density	Acceptable	50748202 & EPA Form 8570-36
830.7370	Dissociation constants in water	Not required for MUP or EP	Not applicable	N/A
830.7520	Particle size	Not required for MUP or EP	Not applicable	N/A
830.7550/ 7560/ 7570	Partition coefficient	Not required for MUP or EP	Not applicable	N/A
830.7840/ 7860	Water solubility	Not required for MUP or EP	Not applicable	N/A
830.7950	Vapor pressure	Not required for MUP or EP	Not applicable	N/A

CONFIDENTIAL ATTACHMENT

